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| APPLICATION NO.        | FILING DATE                             | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---|----------------------|---------------------|------------------|
| 10/743,667             | 12/22/2003                              | John Collier         | ETH-5115            | 7614             |
| 27777<br>PHILIP S. JOH | 7590 04/27/200<br>INSON                 | EXAMINER             |                     |                  |
| JOHNSON & .            |   | POUS, NATALIE R      |                     |                  |
|                        | N & JOHNSON PLAZ<br>WICK, NJ 08933-7003 | A                    | .ART UNIT           | PAPER NUMBER     |
|                        | ,                                       |                      | 3731                |                  |
|                        |   |                      |                     |                  |
| SHORTENED STATUTOR     | RY PERIOD OF RESPONSE                   | MAIL DATE            | DELIVERY MODE -     |                  |
| 3 MC                   | ONTHS                                   | 04/27/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|  | Application No.  | Applicant(s)   |  |  |  |  |
|--|--|----------------|--|--|--|--|
| Office Action Summany  | 10/743,667   | COLLIER ET AL. |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit ,     |  |  |  |  |
|  | Natalie Pous   | 3731           |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |                |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                |  |  |  |  |
| Status   |  |                |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 Fe   | ebruary 2007.  |                |  |  |  |  |
|  |  |                |  |  |  |  |
| 3) Since this application is in condition for allowar  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                |  |  |  |  |
| closed in accordance with the practice under E   | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.                  |                |  |  |  |  |
| Disposition of Claims  |  |                |  |  |  |  |
| 4) Claim(s) 1,3,4 and 7-14 is/are pending in the a   | oplication.  |                |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                |  |  |  |  |
| 6) Claim(s) 1,4,1,10-14 is/are rejected.   |  | ·              |  |  |  |  |
| 7)⊠ Claim(s) 3,8 and 9 is/are objected to.   |  |                |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.  |                |  |  |  |  |
| Application Papers   |  |                |  |  |  |  |
| 9) The specification is objected to by the Examine   | r  | ·              |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acc   |  | Examiner.      |  |  |  |  |
| Applicant may not request that any objection to the  |  |                |  |  |  |  |
| Replacement drawing sheet(s) including the correct   | • • •  |                |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                |  |  |  |  |
| Attachment(s)  1) ☒ Notice of References Cited (PTO-892)  2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/22/03.  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   | ite            |  |  |  |  |

Office Action Summary

### **DETAILED ACTION**

### Response to Arguments

### Regarding the combination of Kletschka and Pierce

Applicant's arguments, see response, filed 2/12/07, with respect to the rejection(s) of the claim(s) under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Fuchs, see below.

# Regarding Claim 14

Applicant's arguments filed 2/11/07 have been fully considered but they are not persuasive. Applicant traverses examiners rejection based on the assertion that in order to have a suture site, the act of suturing must have been completed, and that the present invention requires that the suture anchoring device be located in the proximity of a suture site prior to introducing the suture into the opening of the first retaining member. Examiner notes that the limitation requiring that the suture anchoring device be located in the proximity of a suture site prior to introducing the suture into the opening of the first retaining member is not a limitation as set forth by the claims, and thus arguments with respect to this limitation are moot. However, regarding the limitation that in order to have a suture site, the act of suturing must have been completed, examiner notes that the term "suture site" is not defined in the specification, and thus may be interpreted as a site where suturing is to take place as well as a site where the act of suturing has been completed. Thus, examiner sustains the previous

35 USC 103(a) rejection of claim 14 with respect to the combination of Kletschka and Lyons.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

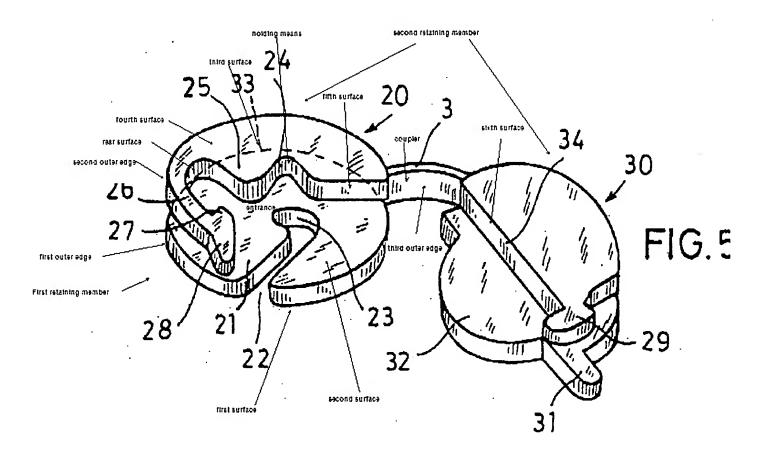
Claims 1, 4, 7, 11, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuchs et al. (US 4291698).

Regarding Claim 1, Fuchs teaches a suture anchoring device comprising: a first retaining member (21) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening that extends from the first outer edge to an inner point of the first retaining member; a second retaining member having a third surface, a fourth surface, a fifth surface, a sixth surface\_and a second outer edge; where the third surface lies in a second plane, and the fifth surface and the sixth surface lie nominally perpendicular to the second outer edge at their lines of intersection therewith; a holding means positioned within the second retaining member, the holding means comprised of an opening extending from the fifth or the sixth surface to within the second retaining member; and a coupler having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first

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retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and the third surface; wherein the second and third surfaces are parallel to each other and non-coterminous (see fig. 5 below).



Alternatively, with respect to figures 1-3 regarding Claim 1, Fuchs teaches a suture anchoring device comprising: a first retaining member (4) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the

first retaining member having an opening (7) that extends from the first outer edge to an inner point of the first retaining member; a second retaining member (1) having a third surface, a fourth surface, a fifth surface, a sixth surface and a second outer edge (11); where the third surface lies in a second plane, and the fifth surface and the sixth surface lie nominally perpendicular to the second outer edge at their lines of intersection therewith; a holding means (defined by portions 8 and 9) positioned within the second retaining member, the holding means comprised of an opening extending from the fifth or the sixth surface to within the second retaining member; and a coupler having (fig. 3) a third outer edge and a cross-sectional area

taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and the third surface (fig. 3); wherein the second and third surfaces are parallel to each other and non-coterminous (fig. 2).

Regarding Claim 4, Fuchs teaches the suture anchoring device of claim 1, where the opening (22) on the first retaining member extends from the second surface to the first surface (fig. 5).

Regarding claim 7, Fuchs teaches the suture anchoring device of claim 1, where the holding means opening further comprises an entrance and a rear surface and the width of the entrance is less than the width of the rear surface (fig. 5).

Regarding Claim 10, Fuchs (fig. 2) teaches the device of claim 2, wherein the cross sectional area of the first retaining member (4) is larger than the cross sectional area of the second retaining member (1).

Regarding Claim 11, Fuchs teaches the suture anchoring device of claim 1, wherein the cross-sectional area of the first retaining member (21) taken in a plane parallel to the first plane is smaller than the cross sectional area of the second retaining member (20,30) taken in a parallel plane (fig. 4).

Regarding Claim 12, Fuchs teaches the suture anchoring device of claim 1, where the cross-sectional area of the first retaining member taken in a plane parallel to the first plane is substantially the same as the cross-sectional area of the second retaining member taken in a parallel plane (fig. 5).

Regarding Claim 13, Fuchs teaches he suture anchoring device of claim 1 where surfaces and corners are rounded (Fig. 5).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kletschka in view of Lyons et al. (US 2004/0260344)

Kletschka teaches a method of securing a suture used in a surgical procedure comprising the steps of: (a) locating a suture anchoring device (10e) in the proximity of a suture site, the suture anchoring device comprising: a first retaining member (24e) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first outer edge to at least partially through the second surface to an inner point of the first retaining member; a second retaining member (18e) having a third surface, a fourth surface and a second outer edge; where the third surface lies in a second plane, the second retaining member having a holding means (19e); a coupler (23e) having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous (fig. 7); (c) wrapping the suture (11e) around the third outer edge of the coupler (23e); and (d) introducing the suture into the holding means (fig. 7). Kletschka fails to teach introducing the suture into said opening. Lyons teaches a suture anchor comprising an

opening (36) and a holder (22), wherein the suture is introduced to both the introducer and the holder (fig. 10) in order to securely attach the suture to the anchor. It would have been an obvious to one of ordinary skill in the art at the time the invention was made to introduce the suture to the opening as well as the holder in order to aid in securing the suture to the anchor as taught by Lyons, since Kletschka has disclosed that the suture may be introduced to either the holder or the opening.

# Allowable Subject Matter

Claims 3 and 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP 4/25/07

ANHTUANT. NGUYEN
SUPERVISORY PATENT EXAMINER